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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

INNOVATIVE BIODEFENSE, INC., ET
AL.,

Defendants.

No. 8:18 CV 996-DOC (JDE)

**DECLARATION OF HEATH R.
HARLEY**

Oral Argument Waived

I, Heath R. Harley, hereby declare as follows:

1. I am a Consumer Safety Officer in the Office of Unapproved Drugs and Labeling Compliance, Division of Unapproved New Drugs, Over-the-Counter (“OTC”) Drugs Branch, Office of Compliance, Center for Drug Evaluation and Research (“CDER”), at the Food and Drug Administration (“FDA”), United States Department of Health and Human Services, located at 10903 New Hampshire Avenue, Silver Spring, MD 20993. I have held this position since September 2007.

2. Prior to becoming a Consumer Safety Officer for CDER, I was an Investigator/Consumer Safety Officer in the Baltimore District Office for FDA's Office of Regulatory Affairs from November 2000 to September 2007.

3. In my current role, I am responsible for collecting, documenting, reviewing, and evaluating drug product labels and labeling (including websites), promotional materials, and other scientific and regulatory information to determine whether drugs are being marketed in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (“FDCA” or the “Act”), 21 U.S.C. § 301 *et seq.*, and its implementing regulations.

4. I am making this declaration in support of the government’s motion for summary judgment, which seeks to enjoin Innovative Biodefense, Inc. (“IBD”), Colette Cozean (“Defendant Cozean”), and Hotan Barough (“Defendant Barough”) (collectively, “Defendants”) from distributing unapproved new drugs in interstate commerce.

5. The statements made in this declaration are based upon my personal knowledge and information about which I have become knowledgeable through my review of official agency records in the course of my responsibilities as a Consumer Safety Officer.

Zylast Products

6. Defendants market and distribute several products under the Zylast name, including, but not limited to, a hand sanitizer called Zylast Broad Spectrum Antimicrobial Antiseptic (“Zylast Antiseptic”), a lotion called Zylast XP (Extended Protection) Antiseptic Lotion (“Zylast Lotion”), and a foaming soap called Zylast XP (Extended Protection) Antiseptic Foaming Soap (“Zylast Soap”) (hereafter, collectively, the “Zylast products”).

Labels on the Zylast Products

7. I reviewed and am familiar with the labels on Zylast Antiseptic, Zylast Lotion, and Zylast Soap. *See* James P. Stallings Declaration (Stallings Decl.) Exhibits 1-3.

8. The labels on the Zylast products bear the text, “Manufactured for Innovative Biodefense Inc. . . . www.zylast.com.” *See* Stallings Decl. Exhibit 1 at GOV-00001743, Exhibit 2 at GOV-00001753, and Exhibit 3 at GOV-00001762.

9. Additionally, the labels contain the following use: “Handwash to decrease bacteria on the skin that potentially can cause disease.” *See* Stallings Decl. Exhibit 1 at GOV-00001743, Exhibit 2 at GOV-00001753, and Exhibit 3 at GOV-00001762.

Defendants’ Websites and Social Media Accounts

10. I have also reviewed and am familiar with the websites and social media accounts associated with the Zylast products, including www.zylast.com (hereafter “[zylast.com](http://www.zylast.com)”), www.zylastdirect.com (hereafter “[zylastdirect.com](http://www.zylastdirect.com)”), www.facebook.com/ZylastXP, (hereafter “IBD’s Facebook page”), and twitter.com/zylastxp (hereafter the “Zylast Twitter feed”).

11. From 2015 through 2019, I used an official FDA computer to review zylast.com, zylastdirect.com, IBD’s Facebook page, and the Zylast Twitter feed. I documented my review of these websites and social media accounts by taking screenshots of the sites. When reviewing these websites and social media accounts, I found that I could access various materials, such as articles and abstracts, via hyperlinks or web addresses found on the sites. I documented the materials I accessed by taking screenshots of them or downloading them.

12. After taking screenshots or downloading materials, I saved the relevant portions of the websites, social media accounts, and materials. On occasion, to help me track statements describing uses for the Zylast products on these sites and in the materials, I would highlight statements in the screenshots and/or insert a red box with a

1 number inside. In the paragraphs below, I have indicated the screenshots or materials on
2 which I added highlighting or boxes.

3 13. During my review of zylast.com, zylastdirect.com, IBD's Facebook page,
4 and the Zylast Twitter feed, I found that these sites explain the uses of the Zylast
5 products, supplement the Zylast products' labels, encourage consumers to buy the
6 products, and provide a means for consumers to order such products.

7 14. At the top right corner of zylast.com is a prominent icon with the text "Buy
8 Now" in large font, and the text "Visit ZylastDirect.com to order" immediately below
9 the icon. A true and correct copy of zylast.com/products, as it appeared on September 8,
10 2019, is attached hereto as Exhibit 1 at GOV-00027981.

11 15. When you click on the "Buy Now" icon, visitors to zylast.com are
12 automatically taken to zylastdirect.com, where they can purchase the Zylast products.
13 True and correct copies of zylastdirect.com/cart and zylastdirect.com/catalog, as they
14 appeared on September 13, 2019, are attached hereto as Exhibit 2 at GOV-00028236
15 through -28243.

16 16. Zylastdirect.com is the only website to which zylast.com directs potential
17 customers for purchasing the Zylast products.

18 17. Only Zylast products are offered for sale on zylastdirect.com. Exhibit 2 at
19 GOV-00028240 through -28243 (accessed on Sept. 13, 2019).

20 18. As of March 2019, zylastdirect.com contained a hyperlink to IBD's
21 Facebook page and the Zylast Twitter feed. A true and correct copy of zylastdirect.com,
22 as it appeared on March 11, 2019, is attached hereto as Exhibit 3 at GOV-00017986
23 (highlighting and red box added).

24 19. As of May 2019, zylast.com contained a hyperlink to IBD's Facebook page.
25 A true and correct copy of a portion of zylast.com, as it appeared on May 13, 2019, is
26 attached hereto as Exhibit 4 at GOV-00020630 (highlighting added).

20. The Zylast Twitter feed, as of March 2019, and IBD's Facebook page, as of May 2019, provided the web address for zylastdirect.com. True and correct copies of twitter.com/ZylastXP/status as it appeared on March 17, 2019, and a portion of facebook.com/ZylastXP/posts, as it appeared on May 29, 2019, are attached hereto as Exhibit 5 at GOV-00018264 (highlighting added) and GOV-00020608 (highlighting added).

21. Additionally, as of May 2019, IBD's Facebook page contained an "About" section that listed IBD's phone number and email address and the zylast.com website address. A true and correct copy of facebook.com/pg/ZylastXP/about, as it appeared on May 29, 2019, is attached hereto as Exhibit 5 at GOV-00020628.

22. In August 2019, I attempted to access IBD's Facebook page and the Zylast Twitter feed and I was not able to access either site.

Defendants' Stated Uses for the Zylast Products

23. In addition to the use for the Zylast products stated on the labels and discussed in paragraph 9, I observed and documented multiple additional statements, found on or available through zylast.com, zylastdirect.com, IBD's Facebook page, and the Zylast Twitter feed regarding how the Zylast products may be used.

24. I took screenshots and downloaded materials regarding the Zylast products on multiple occasions from 2015 to 2019, including, but not limited to, in January 2015, March 2015, April 2015, May 2015, May 2018, June 2018, July 2018, August 2018, October 2018, November 2018, March 2019, May 2019, and September 2019. True and correct copies of portions of the websites, social media accounts, and materials, as they appeared on the dates I accessed them, are attached hereto as Exhibits 6 through 80.

25. As detailed below, my review of these websites, social media accounts, and materials accessed through the websites and social media accounts revealed statements made by Defendants that the Zylast products may be used to reduce or prevent infection, illness, or illness outbreaks from disease-related pathogens.

Statements on Zylast.com

26. Statements found on or available through zylast.com describe multiple uses for the Zylast products, including but not limited to, the following:

a. “Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!”
Exhibit 6 at FDA_APR2019-00000129 (accessed on Mar. 26, 2015); Exhibit 7 at GOV-00001998 (accessed on Apr. 28, 2015);

b. “Adding Zylast Antiseptic Lotion and Foaming Soap to schools, was shown to reduce illness outbreaks by 87.5% in a 4-month, crossover study.”
Exhibit 6 at FDA_APR2019-00000129 (accessed on Mar. 26, 2015); Exhibit 7 at GOV-00001998 (accessed on Apr. 28, 2015);

c. “MRSA is a dangerous, drug-resistant bacteria that is a growing issue in hospitals, nursing homes, prisons, gyms, and in communities. Zylast was tested against MRSA out to six hours after application, with both products destroying more than 90% of MRSA one hour after they had been applied.”
Exhibit 6 at FDA_APR2019-00000129 (accessed on Mar. 26, 2015); Exhibit 7 at GOV-00001998 (accessed on Apr. 28, 2015);

d. “Zylast has been shown to reduce illness in hospitals, nursing homes, and schools.”
Exhibit 8 at GOV-00001849 (accessed on Aug. 27, 2018); Exhibit 9 at GOV-00007936 (accessed on Nov. 6, 2018) (highlighting added);

e. ““Zylast been able to successfully combat the spread of infection . . . our staff has eagerly adopted the product.” -Ryan O.”
Exhibit 8 at GOV-00001849 (accessed on Aug. 27, 2018); Exhibit 9 at GOV-00007936 (accessed on Nov. 6, 2018) (highlighting added);

1 f. “Winner Fighting Ebola Grand Challenge: Because of persistent
2 efficacy, testing against viruses, and clinical studies showing a
3 reduction in illness outbreaks, Zylast was awarded a winner by
4 experts from the CDC, White House, USAID, and the Pentagon
5 as a ‘breakthrough innovation’ in hand hygiene.”

6 Exhibit 8 at GOV-00001849 (accessed on Aug. 27, 2018); Exhibit 9 at GOV-00007936
7 (accessed on Nov. 6, 2018) (highlighting added);

8 g. “Clinical Benefit: Shown to reduce hospital infections by
9 23.1%, illness in schools by 39%, and illness outbreaks by
10 almost 90% when used in real-world settings.”

11 Exhibit 8 at GOV-00001849 (accessed on Aug. 27, 2018); Exhibit 9 at GOV-00007936
12 (accessed on Nov. 6, 2018) (highlighting added);

13 h. “Shown to Kill > 99% of Norovirus surrogate.”
14 Exhibit 8 at GOV-00001849 (accessed on Aug. 27, 2018) (footnote omitted); Exhibit 9
15 at GOV-00007936 (accessed on Nov. 6, 2018) (footnote omitted) (highlighting added);

16 i. “Beth McNichol, PhD ‘First, the Zylast products are persistent
17 for six hours, so children are protected beyond the 15-second
18 lifespan of an alcohol sanitizer. Second, the Zylast Lotion is
19 effective against pathogens like the Norovirus, rotavirus, and the
20 common cold – some of the most prevalent diseases among
21 children, and germs against which alcohol sanitizers are
22 relatively ineffective.”

23 Exhibit 10 at GOV-00018864 (accessed on Aug. 27, 2018) (highlighting added); Exhibit
24 11 at GOV-00007942 (accessed on Nov. 6, 2018) (highlighting added);

25 j. “Annie Pryor, PhD, Stop the Stomach Flu ‘Zylast Antiseptic is a
26 very exciting new hand sanitizer that kills the norovirus surrogate
27 Feline calicivirus 99.97%! It also possesses some residual
28

activity and has been shown to continue working for about 6
hours against bacteria.”

Exhibit 10 at GOV-00018864 (accessed on Aug. 27, 2018) (highlighting added); Exhibit
11 at GOV-00007943 (accessed on Nov. 6, 2018) (highlighting added); Exhibit 12 at
GOV-00027985 (accessed on Sept. 8, 2019);

k. “Zylast Foaming Soap showed substantially better persistent
effect when tested against both *E.coli* (gram negative) and *MRSA*
(gram positive) bacteria.”

Exhibit 13 at GOV-00007940 (accessed on Nov. 6, 2018) (highlighting added); Exhibit
14 at GOV-00027981 (accessed on Sept. 8, 2019);

l. “Zylast Antiseptic is the first hand sanitizer proven to reduce
hospital-acquired infection in a controlled, crossover clinical
trial.”

Exhibit 13 at GOV-00007940 (accessed on Nov. 6, 2018) (highlighting added); Exhibit
14 at GOV-00027981 (accessed on Sept. 8, 2019);

m. “In clinical studies, Zylast has reduced illness in hospitals,
nursing homes, and schools.”

Exhibit 15 at GOV-00027979 (accessed on Sept. 8, 2019);

n. “Proven Clinical Benefit[:] Zylast has proven to be superior to
traditional alcohol sanitizer in several settings. In a study in
hospitals, replacing a traditional alcohol sanitizer with Zylast
reduced hospital-acquired infections (HAIs) by 20%. . . . This is
the first clinical study in which a specific leave-on sanitizer has
been demonstrated to reduce nosocomial infections over an
alcohol sanitizer.”

Exhibit 15 at GOV-00027979 (accessed on Sept. 8, 2019) (underline in original). The
phrase “In a study in hospitals” (referenced above) was hyperlinked to an article:

1 *Cozean J, Czerwinski S, Cozean C. Reduction of Hospital-Acquired Infections with the*
2 *Use of a Hand Sanitizer with Both Immediate and Persistent Antimicrobial Effect. O.*
3 *Jour. of Inf. Diseases & Epidemiology, 1:1; 22-27, 2017. Exhibit 16 at GOV-00028251*
4 *through -28254 (accessed on Sept. 13, 2019);*

5 o. “Reducing Illness in Nursing Homes[:] In a clinical study,
6 alcohol-based sanitizers in a long-term care facility were
7 replaced with persistent Zylast Antiseptic. Making this change
8 significantly reduced nosocomial infections. Overall, infections
9 were down by 17%, with significant reductions in upper
10 respiratory tract infections, ears/eyes/nose/throat infections, and
11 other infections.”

12 Exhibit 15 at GOV-00027979 (accessed on Sept. 8, 2019) (underline in original). The
13 phrase “In a clinical study” (referenced above) was hyperlinked to an abstract:

14 *Czerwinski S & Cozean J. Use of a Persistent, Water-Based Hand Sanitizer with Anti-*
15 *Viral Properties Reduces Nosocomial Infection in Long Term Care Facility. J. Immunol*
16 *Tech Infect Dis, 6:3, 2017. Exhibit 17 at GOV-00028256 (accessed on Sept. 13, 2019);*

17 p. A bar graph titled “Reduction of Transient E. coli on Human Skin” next to
18 the statement:

19 “Zylast has been tested for persistent effect, demonstrating more
20 than a 99.9% kill level 6 hours after application in independent
21 testing.”

22 Exhibit 15 at GOV-00027979 (accessed on Sept. 8, 2019) (underline in original). The
23 phrase “Zylast has been tested for persistent effect” (referenced above) was hyperlinked
24 to an abstract: *Czerwinski S, Cozean J, Taylor T, McGovern K, Cozean C. Novel*
25 *Persistent Products Significantly Reduce In-Vivo Transmission of Transient Pathogens.*
26 *BIT Annual Global Health Conference, 2016. Exhibit 18 at GOV-00028258 (accessed*
27 *on Sept. 13, 2019);*

1 q. “Reducing Illness Outbreaks by 87.5%[:] Zylast was tested in
2 schools for its ability to prevent illness absenteeism and
3 outbreaks. In the two schools tested, adding Zylast reduced
4 illness absenteeism among students by 39% and among staff by
5 24%. Even more incredibly, illness outbreaks – when more than
6 10% of the class was sick – were reduced by nearly 90%.”
7 Exhibit 15 at GOV-00027980 (accessed on Sept. 8, 2019) (underline in original). The
8 phrase “In the two schools tested” (referenced above) was hyperlinked to an article:
9 *Keeney B, Cozean J, and Cozean C et al, Reducing Illness Absenteeism and Outbreaks*
10 *among Students with Persistent, Water-based Antiseptic Products in a Controlled,*
11 *Crossover Clinical Study. Int. J. Microbiol Infect Dis, 1(2) 2017.* Exhibit 19 at GOV-
12 00028260 through -28264 (accessed on Sept. 13, 2019);

13 r. “Reducing Hospital-Acquired Infections . . . Zylast is the first
14 hand sanitizer to reduce hospital infections in the same trial,
15 showing a reduction of 23.1% in nosocomial infections in a
16 hospital trial of more than 6,000 patients.”

17 Exhibit 15 at GOV-00027980 (accessed on Sept. 8, 2019); and

18 s. The headline “Zylast ‘Best on the Market’ According to Senior Living” and
19 the web address for an article titled “Antimicrobial Hand Sanitizer best on the Market,”
20 with the following statements in the article:

21 “Three types of Zylast products were tested against a range of 25
22 different bacteria. This includes an alcohol-based antiseptic, a
23 water-based antiseptic lotion, and foaming hand soap. Among
24 the bacteria tested was *E. coli*, a leading cause of food poisoning,
25 *S pneumonia*, a primary source of pneumonia and meningitis,
26 and *Acinetobacter baumannii*, drug-resistant bacteria that causes
27 many fatal hospital infections. Testing was also done on *S.*

aureus (MRSA) and vancomycin-resistant *Enterococci* (VRE).

In both incidents, the product destroyed more than 99.99 percent of these bacteria on contact and killed more than 90 percent of both VRE and MRSA one hour later. The Norovirus was another target for the Zylast antiseptic product. It was shown to be more than 100 times more effective against Norovirus than alcohol alone.”

Exhibit 20 at GOV-00028244 through -28246 (accessed on Sept. 13, 2019).

Statements on Zylastdirect.com

27. Statements found on or available through zylastdirect.com describe multiple uses for the Zylast products, including but not limited to, the following:

a. “United States announces that Zylast is one of the winners of the grand challenge to fight ebola PROMO CODE ‘FIGHTING EBOLA’ FOR 10% OFF.”

Exhibit 21 at GOV-00006744 (accessed on Jan. 5, 2015);

b. “Zylast products are specifically formulated to be effective against a broad spectrum of germs to include bacteria (including drug-resistant bacteria such as MRSA), viruses, molds, fungi, and more.”

Exhibit 22 at GOV-00001996 (accessed on Apr. 28, 2015);

c. “Zylast has been shown to be 100 times more effective than alcohol sanitizers against the Norovirus, the cause of the stomach flu, killing 99.97% on contact. BZT and the Zylast actives have also been shown to kill more than 99% of the Rhinovirus (common cold), Rotavirus (diarrhea, especially in children), H1N1, Influenzae, HIV, and Herpes viruses on contact.”

Exhibit 23 at GOV-00002000 through -2001 (accessed on Apr. 28, 2015);

d. “Zylast kills more than 99% of Rhinovirus, the highly contagious
‘common cold’ on contact!”

Exhibit 24 at GOV-00002002 (accessed on Apr. 28, 2015);

e. “Zylast kills influenza, ‘the flu’ and killed 99.99% of the H1N1
strain in 15 seconds!”

Exhibit 25 at GOV-00002003 (accessed on Apr. 28, 2015);

f. “Zylast Eliminates: Norovirus (The Stomach Flu) 99.97% E.
coli 99% MRSA & VRE 99% Cold & Flu Viruses 99%.”

Exhibit 26 at GOV-00002007 (accessed on Apr. 28, 2015);

g. “‘First, the Zylast products are persistent for six hours so children
are protected beyond the 15-second lifespan of an alcohol
sanitizer. Second, the Zylast Lotion is effective against
pathogens like the Norovirus, rotavirus, and the common cold –
some of the most prevalent diseases among children, and germs
against which alcohol sanitizers are relatively ineffective. . . .’
Beth McNichol.”

Exhibit 26 at GOV-00002007 (accessed on Apr. 28, 2015) (describing Beth McNichol as
“M.D., Doctorate in Emerging Infectious Diseases from the Uniformed Services
University of the Health Sciences”); Exhibit 27 at GOV-00002013 (accessed on May 8,
2018) (same); Exhibit 28 at GOV-00007959 (accessed on Nov. 2, 2018) (describing
Beth McNichol as “PhD, Emerging Infectious Disease”) (highlighting added); Exhibit 29
at GOV-00017986 (accessed on Mar. 11, 2019) (same) (highlighting and red box added);

h. “Zylast products are specifically formulated to be effective
against a broad spectrum of germs, including bacteria, viruses,
fungi, molds, and more.”

Exhibit 27 at GOV00002013 (accessed on May 8, 2018); Exhibit 30 at GOV-00017992
(accessed on Mar. 12, 2019) (highlighting and red box added);

1 i. “Zylast is one of the winners of the grand challenge to fight
2 ebola.”
3 Exhibit 31 at GOV-00006976 (accessed on June 18, 2018); Exhibit 32 at GOV-
4 00001860 (accessed on Aug. 27, 2018); Exhibit 33 at GOV-00007951 (accessed on Oct.
5 31, 2018) (highlighting added);

6 j. “Zylast is 100 times more effective against Norovirus ‘the
7 stomach flu’, than alcohol-based sanitizers.”
8 Exhibit 31 at GOV-00006976 (accessed on June 18, 2018); Exhibit 34 at GOV-
9 00001857 (accessed on Aug. 27, 2018); Exhibit 35 at GOV-00007957 (accessed on Oct.
10 31, 2018) (highlighting added);

11 k. “Zylast is effective against Influenza ‘the flu’, Rhinovirus ‘the
12 common cold’, E.coli and more.”
13 Exhibit 36 at GOV-00006978 (accessed on June 18, 2018); Exhibit 37 at GOV-
14 00007956 (accessed on Nov. 2, 2018) (highlighting added); Exhibit 38 at GOV-
15 00017738 (accessed on Mar 11, 2019);

16 l. “Designed to prevent infection in hospitals, nursing homes,
17 schools, and at home.”
18 Exhibit 39 at GOV-00002067 (accessed on July 9, 2018); Exhibit 40 at GOV-00001855
19 (accessed on Aug. 27, 2018); Exhibit 41 at GOV-00007950 (accessed on Oct. 31, 2018)
20 (highlighting added);

21 m. “The extended protection against transient MRSA of the Zylast
22 products has also been evaluated using human skin substitutes
23 in-vitro. The Foaming Soap was compared against other leading
24 market products. Zylast reduced transient MRSA by 100% at 2
25 minutes after being applied and washed off, 93% after 1 hour,
26 and 84% at 6 hours, significantly better than other antimicrobial
27 soaps on the market.”

1 Exhibit 42 at GOV-00017349 (May 8, 2018) (citation omitted) (highlighting added);
2 Exhibit 43 at GOV-00018846 (accessed on Aug. 27, 2018) (citation omitted); Exhibit 44
3 at GOV-00020413 (accessed on Oct. 31, 2018) (citation omitted) (highlighting added);

4 n. A hyperlink to an article titled “Westmont First to Adopt Zylast Sanitizer
5 for a New Level of Campus Clean,” which states:

6 “It has also been successfully tested against the Rotavirus, a
7 common cause of diarrhea among children, and Rhinovirus, the
8 common cold. The active ingredient in Zylast, BZT, has been
9 shown to kill more than 99 percent of other viruses like influenza,
10 HIV and Herpes on contact.”

11 Exhibit 45 at GOV-00018861 (accessed on Aug. 27, 2018); Exhibit 46 at GOV-
12 00001861 through -1862 (accessed on Aug. 27, 2018); Exhibit 47 at GOV-00007961
13 (accessed on Oct. 31, 2018); Exhibit 48 at GOV-00007962 through -7963 (accessed on
14 Oct. 31, 2018) (highlighting added);

15 o. A hyperlink to an article titled “Zylast products show antimicrobial
16 persistence,” which contained the following statements:

17 “Two of the most prevalent and dangerous of these drug-resistant
18 bacteria are Methicillin-Resistant *S. aureus* (MRSA) and
19 Vancomycin-Resistant Enterococci (VRE). Testing was
20 performed with the Zylast antiseptic against both of these deadly
21 bacteria. Not only did the antiseptic destroy more than 99.99%
22 of these bacteria on contact, it was still killing more than 90% of
23 VRE and MRSA one hour after it was applied. . . . Previous
24 testing has also been performed against the H1N1 flu, where the
25 Zylast Antiseptic killed 99.99% of the virus within 15 seconds.
26 . . . Innovative BioDefense, creators of Zylast, believe the
27 combination of increased immediate kill and long-lasting

1 persistence can significantly reduce infection rates in hospitals,
2 nursing homes, schools, and businesses.”

3 Exhibit 45 at GOV-00018861 (accessed on Aug. 27, 2018); Exhibit 49 at GOV-
4 00001863 through -1864 (accessed on Aug. 27, 2018); Exhibit 47 at GOV-00007961
5 (accessed on Oct. 31, 2018); Exhibit 50 at GOV-00007964 through -7965 (accessed on
6 Oct. 31, 2018) (highlighting added);

7 p. A hyperlink to an article titled “Antimicrobial Hand Sanitizer best on the
8 Market,” which stated:

9 “Three types of Zylast products were tested against a range of 25
10 different bacteria. This includes an alcohol-based antiseptic, a
11 water-based antiseptic lotion, and foaming hand soap. Among the
12 bacteria tested was *E. coli*, a leading cause of food poisoning, *S*
13 *pneumonia*, a primary source of pneumonia and meningitis, and
14 *Acinetobacter baumannii*, drug-resistant bacteria that causes
15 many fatal hospital infections. Testing was also done on *S. aureus*
16 (MRSA) and vancomycin-resistant *Enterococci* (VRE). In both
17 incidents, the product destroyed more than 99.99 percent of these
18 bacteria on contact and killed more than 90 percent of both VRE
19 and MRSA one hour later. The Norovirus was another target for
20 the Zylast antiseptic product. It was shown to be more than 100
21 times more effective against Norovirus than alcohol alone.”

22 Exhibit 47 at GOV-00007961 (accessed on Oct. 31, 2018); Exhibit 51 at GOV-00007968
23 through -7969 (accessed on Oct. 31, 2018) (highlighting added);

24 q. “‘Zylast been able to effectively combat the spread of infection,
25 our staff has eagerly adopted the product. . . .’ Ryan O.”

26 Exhibit 52 at GOV-00017771 (accessed on Mar. 11, 2019) (highlighting added);
27

1 r. “Zylast has been shown in controlled clinical studies to prevent
2 nearly 90% of illness outbreaks in schools and reduce illness
3 absenteeism by 39%.”

4 Exhibit 53 at GOV-00017998 (accessed on Mar. 12, 2019) (citation omitted)
5 (highlighting and red box added);

6 s. “In initial clinical trials, Zylast was shown to reduce HAIs by
7 23.1% over handwashing alone, the only sanitizer ever to show
8 the ability to reduce infections.”

9 Exhibit 54 at GOV-00018006 (accessed on Mar. 17, 2019) (citation omitted)
10 (highlighting and red box added); and

11 t. “MRSA is a variation of *S. aureus* that has mutated to be resistant
12 to a specific strain of antibiotics, but that has no effect on topical
13 antimicrobials. All Zylast products have been tested for
14 immediate kill against *S. Aureus*.”

15 Exhibit 55 at GOV-00017994 (accessed on Mar. 12, 2019) (citation omitted)
16 (highlighting and red box added).

17 **Statements on IBD’s Facebook Page**

18 28. Statements found on or available through IBD’s Facebook Page describe
19 multiple uses for the Zylast products, including but not limited to, the following:

20 a. A December 13, 2014 post containing a hyperlink to a December 12, 2014
21 press release titled “Zylast™ Wins USAID ‘Fighting Ebola Grand Challenge,’” stating:

22 “Immediate Kill and 6-hour Persistence Likely to Prevent Ebola
23 Infections . . . The persistence of Zylast is critical in fighting the
24 spread of Ebola. If a healthcare worker comes into contact with
25 an infected person . . . Zylast provides defense against infection.
26 . . . Zylast kills any Ebola virus that comes into contact with
27 Zylast-treated skin and will persist up to 6 hours after

1 application. . . . Zylast has been proven to kill Norovirus, HIV,
2 Poliovirus, all Influenzae including H1N1, Herpes Simplex,
3 Rhinovirus, Rotavirus, and many others. . . . This would
4 confirm the ability of Zylast in conjunction with other protective
5 equipment to reduce Ebola infection. . . . ‘Zylast has the
6 potential to contain the spread of Ebola,’ according to Dr. Beth
7 McNicol, who holds her PhD in Emerging Infectious Disease. . .
8 . The current Ebola outbreak began in December of 2013, and
9 has spread through the West African countries of Guinea,
10 Liberia, and Sierra Leone. . . . Zylast can be bought by
11 consumers over the Internet at Amazon, or at numerous other
12 sites. It is also available at www.zylastdirect.com . . . (code:
13 FightingEbola).”

14 Exhibit 56 at GOV-00002074 (accessed on May 6, 2015); Exhibit 57 at GOV-00002075
15 through -2076 (accessed on May 6, 2015); Exhibit 58 at GOV-00008003 (accessed on
16 Oct. 30, 2018) (highlighting added); Exhibit 59 at GOV-00008004 through -8006
17 (accessed on Oct. 30, 2018) (highlighting added); Exhibit 60 at GOV-00020609
18 (accessed on May 29, 2019) (highlighting added); Exhibit 61 at GOV-00020610 through
19 -20612 (accessed on May 29, 2019) (highlighting added);

20 b. A December 15, 2014 post stating:

21 “With Zylast winning the National Fighting Ebola Grand
22 Challenge, we want to offer the same protection to all of our
23 customers over the flu season. Head to ZylastDirect.com and use
24 the coupon code FightingEbola to save 10% on Zylast. Makes a
25 great stocking stuffer!”

26 Exhibit 62 at GOV-00006749 (accessed on Jan. 5, 2015); Exhibit 56 at GOV-00002074
27 (accessed on May 6, 2015); Exhibit 58 at GOV-00008003 (accessed on Oct. 30, 2018)

(highlighting added); Exhibit 63 at GOV-00020608 (accessed on May 29, 2019)
(highlighting added);

c. A December 23, 2014 post containing a hyperlink to an article titled “Lake Forest company’s antiseptic sanitizer may help in Ebola fight,” stating:

“Many-layered protective suits help health care workers who are treating patients avoid exposure to Ebola, but each time they disrobe, the risk of infection returns. . . . ‘Health care workers fighting the epidemic in Africa . . . could apply Zylast before donning garb and still be protected against infection during removal’ [Colette] Cozean said.”

Exhibit 64 at GOV-00008008 (accessed on Oct. 31, 2018) (highlighting added); Exhibit 65 at GOV-00008009 through -8010 (accessed on Oct. 31, 2018) (highlighting added); Exhibit 66 at GOV-00020614 (accessed on May 29, 2019) (highlighting added); Exhibit 67 at GOV-00020615 through -20616 (accessed on May 29, 2019) (highlighting added);

d. A March 1, 2015 post stating:
“New Zylast article picked up by Sound Medicine at NPR – a potential new tool in the fight against Ebola and disease. Powerful enough for Ebola, safe enough for your family!”

Exhibit 68 at GOV-00002071 (accessed on May 6, 2015);

e. A March 4, 2015 post stating:
“Zylast: New Antibacterial Cleanser May Help Knock out Ebola - . . .”

Exhibit 69 at GOV-00002070 (accessed on May 6, 2015);

f. A February 6, 2017 post stating:
“Think your traditional alcohol sanitizer is helping prevent the spread of the flu or cold in your house? Think again – multiple studies have shown that standard alcohol sanitizers don’t reduce

1 the spread of respiratory infections in homes. See why Zylast is
2 the most advanced hand sanitizer on the market, and why the
3 Zylast Antiseptic is recommended by the StopTheStomachFlu
4 website! Use the coupon code ‘Healthy2017’ at
5 www.ZylastDirect.com for 10% off your order.”

6 Exhibit 70 at GOV-00020520 (accessed on May 29, 2019);

7 g. A January 27, 2018 post stating:

8 “A video made by our friends at Stop the Stomach Flu – see why
9 the Zylast Antiseptic is one of the only products they
10 recommend! Use the coupon code ‘StopNorovirus’ to save 10%
11 on your order at www.ZylastDirect.com/buy today!”

12 Exhibit 70 at GOV-00020518 (accessed on May 29, 2019); and

13 h. Profile picture stating:

14 “Zylast Winner FIGHTING EBOLA GRAND CHALLENGE.”

15 Exhibit 70 at GOV-00020518 (accessed on May 29, 2019).

16 **Statements on the Zylast Twitter Feed**

17 29. Statements found on or available through the Zylast Twitter feed describe
18 multiple uses for the Zylast products, including but not limited to, the following:

19 a. A July 16, 2013 tweet stating:

20 “Zylast Retweeted MRSA INFECTION [@mrsainfection] Zylast
21 products show antimicrobial persistence dlvr.it/3fzyLK #mrsa.”

22 Exhibit 71 at GOV-00008015 (accessed on Oct. 31, 2018) (highlighting added); Exhibit
23 72 at GOV-00018266 (accessed on Mar. 19, 2019) (highlighting added);

24 b. A September 29, 2013 tweet stating:

25 “We are making big noise in the world of #infectiousdisease!
26 #Zylast is the ONLY hand sanitizer effective in killing the #flu
27 and #MRSA.”

Exhibit 73 at GOV-00002082 (accessed on May 6, 2015); Exhibit 74 at GOV-00008014 (accessed on Oct. 31, 2018) (highlighting added); Exhibit 75 at GOV-00018265 (accessed on Mar. 19, 2019) (highlighting added);

c. A July 21, 2014 tweet stating:

“Zylast is more than 100 times as effective against the Norovirus as alcohol sanitizers, preventing nearly 90% of . . .”

Exhibit 76 at GOV-00002080 (accessed on May 6, 2015); Exhibit 77 at GOV-00002018 (accessed on May 8, 2018); Exhibit 78 at GOV-00008013 (accessed on Oct. 31, 2018) (highlighting added); Exhibit 79 at GOV-00018264 (accessed on Mar. 17, 2019) (highlighting added); and

d. A March 1, 2015 tweet stating:

“New Zylast article picked up by Sound Medicine at NPR – a potential new tool in the fight against Ebola and . . .”

Exhibit 80 at GOV-00002079 (accessed on May 6, 2015).

Statements in Other Zylast Marketing Materials

30. On August 20, 2019, I used an official FDA computer to visit a third party Zylast distributor’s website—www.practicalhs.com (the “Practical Hospital Services Website”). True and correct copies of portions of the website and material available through the website, as they appeared on August 20, 2019, are attached hereto as Exhibit 81 at GOV-00027949 through -27961 (highlighting and red boxes added).

31. I reviewed the information about the Zylast products contained on this website, including a hyperlinked document titled “Benefits of Zylast in Healthcare,” which states:

“Zylast was shown to kill 99.97% of the Norovirus surrogate on human skin on contact. Zylast, or it’s [sic] active ingredient, has also been shown to kill more than 99% of HIV, influenza, H1N1, Rotavirus, Rhinovirus, Herpes, and others on contact in studies.”

Exhibit 81 at GOV-00027956 (accessed Aug. 20, 2019) (footnotes omitted) (highlighting and red box added).

Zylast Product Distribution


32. I also reviewed documents produced by Defendants in response to the Government's discovery requests in this litigation. Exhibit 82 at IBD_00001779 through -1781.¹ Specifically, I reviewed a February 14, 2019 email from Gail Montenegro to Hotan Barough with the subject "Sales Order 1576 from Innovative BioDefense, Inc." stating: "Can you please ship this out again?" Exhibit 82 at IBD_00001779. Attached to this email were: (1) a packing slip for Sale Order 1576 for Zylast Antiseptic Foaming Soap with the shipping address listed as "Pittsburgh #15 . . . Leetsdale, PA 15056"; and (2) a UPS label with the sender's address listed as "Colette Cozean Innovative BioDefense, Inc. 21581 Midcrest Dr Lake Forest CA 92630" and the recipient's address listed as "Pittsburgh #15 . . . Leetsdale, PA 15056." Exhibit 82 at IBD_00001780 through -1781. The tracking number provided on this UPS label was 1Z 609 Y06 03 9996 8698. Exhibit 82 at IBD_00001781.

33. On March 20, 2019, I visited www.ups.com, entered the tracking number listed above, and the website showed that UPS delivered the package associated with that tracking number to Leetsdale, Pennsylvania, on March 4, 2019. A true and correct copy of the tracking information available on www.ups.com/track, as it appeared on March 20, 2019, is attached hereto as Exhibit 83 at FDA_APR2019_00000157 through -163.

¹ I understand that copies of these documents (IBD_00001779 through -1781) are also attached to the Declaration of Douglas Ross.

1 I declare under penalty of perjury that the foregoing is true and correct. 28 U.S.C.
2 § 1746.

3
4 Executed on September 30, 2019.

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6 
7 HEATH R. HARLEY
8 Consumer Safety Officer
9 Office of Unapproved Drugs and Labeling
10 Compliance
11 Office of Compliance
12 Center for Drug Evaluation and Research
13 United States Food and Drug Administration
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Appendix: List of Exhibits

Exhibit No.	Description
1	Screenshot of https://www.zylast.com/products (accessed on Sept. 8, 2019) GOV-00027981 through -27982
2	Screenshots of https://www.zylastdirect.com/cart.php and https://www.zylastdirect.com/catalog.php (accessed on Sept. 13, 2019) GOV-00028236 through -00028243
3	Screenshot of https://www.zylastdirect.com/ (accessed on Mar. 11, 2019) GOV-00017985 through -17986
4	Screenshot of a portion of https://www.zylast.com (accessed on May 13, 2019) GOV-00020630
5	Screenshots of https://twitter.com/ZylastXP/status/491454053532962816 (accessed on Mar. 17, 2019), a portion of https://www.facebook.com/ZylastXP/posts/ (accessed on May 29, 2019), and https://www.facebook.com/pg/ZylastXP/about (accessed on May 29, 2019) GOV-00018264, -20608, and -20628 through -20629
6	Screenshot of a portion of http://www.zylast.com/TheScience.aspx (accessed Mar. 26, 2015) FDA_APR2019-00000128 through -129
7	Screenshot of a portion of http://www.zylast.com/TheScience.aspx

	(accessed on Apr. 28, 2015) GOV-00001997 through -1998
8	Screenshot of a portion of https://www.zylast.com/ (accessed on Aug. 27, 2018) GOV-00001849
9	Screenshot of a portion of https://www.zylast.com/ (accessed on Nov. 6, 2018) GOV-00007936
10	Screenshot of https://www.zylast.com/testimonials (accessed on Aug. 27, 2018) GOV-00018863 through -18864
11	Screenshot of a portion of https://www.zylast.com/testimonials (accessed on Nov. 6, 2018) GOV-00007942 through -7943
12	Screenshot of https://www.zylast.com/testimonials (accessed on Sept. 8, 2019) GOV-00027984 through -27985
13	Screenshot of a portion of https://www.zylast.com/products (accessed on Nov. 6, 2018) GOV-00007940
14	Screenshot of https://www.zylast.com/products (accessed on Sept. 8, 2019) GOV-00027981 through -27982
15	Screenshot of https://www.zylast.com/the-science (accessed on Sept. 8, 2019) GOV-00027979 through -27980

16	Article accessed from hyperlink on zylast.com: <i>Cozean J, Czerwinski S, Cozean C. Reduction of Hospital-Acquired Infections with the Use of a Hand Sanitizer with Both Immediate and Persistent Antimicrobial Effect. O. Jour. of Inf. Diseases & Epidemiology, 1:1; 22-27, 2017</i> (accessed on Sept. 13, 2019) GOV-00028251 through -28254
17	Abstract accessed from hyperlink on zylast.com: <i>Czerwinski S & Cozean J. Use of a Persistent, Water-Based Hand Sanitizer with Anti-Viral Properties Reduces Nosocomial Infection in Long Term Care Facility. J. Immunol Tech Infect Dis, 6:3, 2017</i> (accessed on Sept. 13, 2019) GOV-00028256
18	Abstract accessed from hyperlink on zylast.com: <i>Czerwinski S, Cozean J, Taylor T, McGovern K, Cozean C. Novel Persistent Products Significantly Reduce In-Vivo Transmission of Transient Pathogens. BIT Annual Global Health Conference, 2016</i> (accessed on Sept. 13, 2019) GOV-00028258
19	Article accessed from hyperlink on zylast.com: <i>Keeney B, Cozean J, and Cozean C et al, Reducing Illness Absenteeism and Outbreaks among Students with Persistent, Water-based Antiseptic Products in a Controlled, Crossover Clinical Study. Int. J. Microbiol Infect Dis, 1(2) 2017</i> (accessed on Sept. 13, 2019) GOV-00028260 through -28264
20	Screenshots of https://www.zylast.com/news and an article titled “Antimicrobial Hand Sanitizer best on the Market” accessed using a web address provided on zylast.com/news (accessed on Sept. 13, 2019)

	GOV-00028244 through -28249
21	Screenshot of http://www.zylastdirect.com (accessed on Jan. 5, 2015) GOV-00006744
22	Screenshot of a portion of http://www.zylastdirect.com/work (accessed on Apr. 28, 2015) GOV-00001995 through -1996
23	Screenshot of a portion of http://www.zylastdirect.com/faq (accessed on Apr. 28, 2015) GOV-00002000 through -2001
24	Screenshot of a portion of http://www.zylastdirect.com (accessed on Apr. 28, 2015) GOV-00002002
25	Screenshot of a portion of http://www.zylastdirect.com (accessed on Apr. 28, 2015) GOV-00002003
26	Screenshot of a portion of http://www.zylastdirect.com/school/ (accessed on Apr. 28, 2015) GOV-00002006 through -2007
27	Screenshot of a portion of https://www.zylastdirect.com/school/ (accessed on May 8, 2018) GOV-00002013
28	Screenshot of https://www.zylastdirect.com/ (accessed on Nov. 2, 2018) GOV-00007958 through -7959
29	Screenshot of https://www.zylastdirect.com/ (accessed on Mar. 11, 2019) GOV-00017985 through -17986

30	Screenshot of a portion of https://www.zylastdirect.com/compare/ (accessed on Mar. 12, 2019) GOV-00017992
31	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on June 18, 2018) GOV-00006976
32	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on Aug. 27, 2018) GOV-00001860
33	Screenshot of https://www.zylastdirect.com/ (accessed on Oct. 31, 2018) GOV-00007951 through -7952
34	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on Aug. 27, 2018) GOV-00001857
35	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on Oct. 31, 2018) GOV-00007957
36	Screenshot of https://www.zylastdirect.com/ (accessed on June 18, 2018) GOV-00006978 through -6979
37	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on Nov. 2, 2018) GOV-00007956
38	Screenshot of a portion of https://www.zylastdirect.com/ (accessed on Mar. 11, 2019)

1		GOV-00017738
2	39	Screenshot of a portion of https://www.zylastdirect.com/products/ (accessed on July 9, 2018)
3		GOV-00002067
4		
5	40	Screenshot of a portion of https://www.zylastdirect.com/products/ (accessed on Aug. 27, 2018)
6		GOV-00001855
7		
8	41	Screenshot of a portion of https://www.zylastdirect.com/products/ (accessed on Oct. 31, 2018)
9		GOV-00007950
10		
11	42	Screenshot of https://www.zylastdirect.com/compare/ (accessed on May 8, 2018)
12		GOV-00017348 through -17350
13		
14	43	Screenshot of https://www.zylastdirect.com/compare/ (accessed on Aug. 27, 2018)
15		GOV-00018845 through -18847
16		
17	44	Screenshot of https://www.zylastdirect.com/compare/ (accessed on Oct. 31, 2018)
18		GOV-00020412 through -20414
19		
20	45	Screenshot of https://www.zylastdirect.com/news/ (accessed on Aug. 27, 2018)
21		GOV-00018861 through -18862
22		
23	46	Screenshot of a portion of an article titled “Westmont First to Adopt Zylast Sanitizer for New Level of Campus Clean” accessed from a hyperlink on www.zylastdirect.com/news (accessed on Aug. 27, 2018)
24		GOV-00001861 through -1862
25		
26		
27		

47	Screenshot of a portion of https://www.zylastdirect.com/news/ (accessed on Oct. 31, 2018) GOV-00007960 through -7961
48	Screenshot of a portion of an article titled “Westmont First to Adopt Zylast Sanitizer for New Level of Campus Clean” accessed from a hyperlink on www.zylastdirect.com/news (accessed on Oct. 31, 2018) GOV-00007962 through -7963
49	Screenshot of an article titled “Zylast products show antimicrobial persistence” accessed from a hyperlink on www.zylastdirect.com/news (accessed on Aug. 27, 2018) GOV-00001863 through -1866
50	Screenshot of a portion of an article titled “Zylast products show antimicrobial persistence” accessed from a hyperlink on www.zylastdirect.com/news (accessed on Oct. 31, 2018) GOV-00007964 through -7967
51	Screenshot of a portion of an article titled “Antimicrobial Hand Sanitizer best on the Market” accessed from a hyperlink on www.zylastdirect.com/news (accessed on Oct. 31, 2018) GOV-00007968 through -7969
52	Screenshot of https://www.zylatsdirect.com/ (accessed on Mar. 11, 2019) GOV-00017772 and -17771
53	Screenshot of https://www.zylastdirect.com/at-home/ (accessed on Mar. 12, 2019) GOV-00017997 through -17998
54	Screenshot of https://www.zylastdirect.com/faq/ (accessed on Mar. 17,

	2019) GOV-00018005 through -18006
55	Screenshot of a portion of https://www.zylastdirect.com/compare/ (accessed on Mar. 12, 2019) GOV-00017993 through -17994
56	Screenshot of a portion of https://www.facebook.com/ZylastXP showing a December 13, 2014 post (accessed on May 6, 2015) GOV-00002074
57	Screenshot of an article titled “Zylast Wins USAID ‘Fighting Ebola Grand Challenge’” accessed from hyperlink on www.facebook.com/ZylastXP (accessed on May 6, 2015) GOV-00002075 through -2077
58	Screenshot of a portion of https://www.facebook.com/ZylastXP/ showing a December 13, 2014 post (accessed on Oct. 30, 2018) GOV-00008003
59	Screenshot of a portion of an article titled “Zylast Wins USAID ‘Fighting Ebola Grand Challenge’” accessed from hyperlink on www.facebook.com/ZylastXP (Oct. 30, 2018) GOV-00008004 through -8007
60	Screenshot of a portion of https://www.facebook.com/ZylastXP/posts/ showing a December 13, 2014 post (accessed on May 29, 2019) GOV-00020609
61	Screenshot of an article titled “Zylast Wins USAID ‘Fighting Ebola Grand Challenge’” accessed from hyperlink on www.facebook.com/ZylastXP/posts (accessed on May 29, 2019) GOV-00020610 through -20613

62	Screenshot of https://www.facebook.com/ZylastXP/posts/900638799954881 showing a December 15, 2014 post (accessed on Jan. 5, 2015) GOV-00006749
63	Screenshot of a portion of https://www.facebook.com/ZylastXP/posts/ showing a December 15, 2014 post (accessed on May 29, 2019) GOV-00020608
64	Screenshot of https://www.facebook.com/ZylastXP/posts/ showing a December 23, 2014 post (accessed on Oct. 31, 2018) GOV-00008008
65	Screenshot of an article titled “Lake Forest company’s antiseptic sanitizer may help in Ebola fight” accessed from a hyperlink on www.facebook.com/ZylastXP/posts (accessed on Oct. 31, 2018) GOV-00008009 through -8011
66	Screenshot of a portion of https://www.facebook.com/ZylastXP/posts/ showing a December 23, 2014 post (accessed on May 29, 2019) GOV-00020614
67	Screenshot of an article titled “Lake Forest company’s antiseptic sanitizer may help in Ebola fight” accessed from a hyperlink on www.facebook.com/ZylastXP/posts (accessed on May 29, 2019) GOV-00020615 through -20617
68	Screenshot of a portion of https://www.facebook.com/ZylastXP showing a March 1, 2015 post (accessed on May 6, 2015) GOV-00002071
69	Screenshot of a portion of https://www.facebook.com/ZylastXP showing a March 4, 2015 post (accessed on May 6, 2015)

1		GOV-00002070
2	70	Screenshot of https://www.facebook.com/ZylastXP/ showing a February
3		6, 2017 post, January 27, 2018 post, and the IBD Facebook page profile
4		picture (accessed on May 29, 2019)
5		GOV-00020518 through -20600
6	71	Screenshot of a portion of https://twitter.com/ZylastXP showing a July
7		16, 2013 retweet (accessed on Oct. 31, 2018)
8		GOV-00008015
9	72	Screenshot of a portion of
10		https://twitter.com/mrsainfection/status/357038948905791488 showing
11		a July 16, 2013 retweet (accessed on Mar. 19, 2019)
12		GOV-00018266
13	73	Screenshot of a portion of https://twitter.com/zylastxp showing a
14		September 29, 2013 tweet (accessed on May 6, 2015)
15		GOV-00002082
16	74	Screenshot of a portion of https://twitter.com/ZylastXP showing a
17		September 29, 2013 tweet (accessed on Oct. 31, 2018)
18		GOV-00008014
19	75	Screenshot of a portion of
20		https://twitter.com/ZylastXP/status/384378058657890304 showing a
21		September 29, 2013 tweet (accessed on Mar. 19, 2019)
22		GOV-00018265
23	76	Screenshot of a portion of https://twitter.com/zylastxp showing a July
24		21, 2014 tweet (accessed on May 6, 2015)
25		GOV-00002080
26	77	Screenshot of a portion of https://twitter.com/ZylastXP showing a July
27		

1		21, 2014 tweet (accessed on May 8, 2018)
2		GOV-00002018
3	78	Screenshot of a portion of https://twitter.com/ZylastXP showing a July
4		21, 2014 tweet (accessed on Oct. 31, 2018)
5		GOV-00008013
6	79	Screenshot of https://twitter.com/ZylastXP/status/491454053532962816
7		showing a July 21, 2014 tweet (accessed on Mar. 17, 2019)
8		GOV-00018264
9	80	Screenshot of a portion of https://twitter.com/zylastxp showing a March
10		1, 2015 tweet (accessed on May 6, 2015)
11		GOV-00002079
12	81	Screenshots of portions of https://www.practicalhs.com (“Practical
13		Hospital Services Website”) and marketing material titled “Benefits of
14		Zylast in Healthcare” accessed from a hyperlink on the Practical
15		Hospital Services Website (accessed on Aug. 20, 2019)
16		GOV-00027949 through -27961
17	82	Documents produced by Defendants in discovery that are also attached
18		to the Declaration of Douglas Ross. The documents consist of (1) a
19		February 14, 2019 email from gmontenegro@ischem.com to
20		hotan@zylastdirect.com , (2) a November 11, 2018 packing slip for
21		Zylast Soap, and (3) a UPS Ground shipping label.
22		IBD_00001779 through -1781
23	83	Screenshot of https://www.ups.com/track showing delivery information
24		for tracking number 1Z 609 Y06 03 9996 8698 (accessed on Mar. 20,
25		2019)
26		FDA_APR2019_00000157 through -163

**EXHIBIT 1 TO
DECLARATION OF
HEATH R. HARLEY**



Zylast Products



Antiseptic Lotion 0.2% BZT

Water-based, non-flammable and moisturizing, the Antiseptic Lotion provides rapid, broad-spectrum kill and persistent protection, without irritating the skin.

The Antiseptic Lotion is shown to actually add moisture back into the skin, and improved skin condition by 46% over an alcohol sanitizer when used in a hospital setting. It is the first non-alcohol product to exceed the reference alcohol product in rapid kill testing, and is persistent in the FDA-required testing at six hours.

Available in 1/2 oz tubes, 2 oz bottles, 8 oz bottles, and 1 liter cartridges used inside the proprietary Zylast auto or manual dispensers.



Antiseptic 76% Ethyl Alcohol

The Zylast Antiseptic is an alcohol-based sanitizer, designed for use in hospitals and medical facilities. Unlike traditional alcohol sanitizers, the Zylast Antiseptic offers persistence, demonstrated in testing conducted at six hours after application.

It is also designed with moisturizers and emollients to restore moisture to the skin and reduce irritation with multiple uses. The Zylast Antiseptic is the first hand sanitizer proven to reduce hospital-acquired infection in a controlled, crossover clinical trial.

Available in 2 oz bottles (pictured above), 8 oz bottles, and 1 liter cartridges used inside the proprietary Zylast auto or manual dispensers.



Foaming Soap 0.2% BZT

The Zylast Antiseptic Foaming Soap uses the same proprietary Zylast technology to provide a rapid, broad-spectrum kill of germs with persistence. Filled with moisturizers, it leaves the hands feeling silky and smooth. A light, pleasant citrus scent lingers after use.

When compared against other soaps on the market, the Zylast Foaming Soap showed substantially better persistent effect when tested against both *E. coli* (gram negative) and *MRSA* (gram positive) bacteria in testing conducted at Pace University.

Available in an 8.25 oz pump bottle (pictured above) and in a 1L cartridge to be used inside the proprietary Zylast auto or manual dispensers.



Surgical Scrub 76% Ethyl Alcohol

The Zylast Surgical Scrub is a waterless, alcohol-based scrub that is designed for use between patients, after the surgeon has scrubbed in with a water-aided rinse.

The Zylast Surgical Scrub kills germs on contact and provides persistence for the surgeon and staff. Alcohol-based surgical scrubs have been demonstrated to be substantially less irritating to the skin than traditional surgical scrubs and just as effective in removing germs. Zylast compares favorably in both performance and price to other surgical scrubs on the market.

Available in a 1L cartridge used inside the proprietary Zylast dispensers.



Automatic and Manual Dispensers

Zylast uses proprietary, ADA-compliant wall-mounted dispensers.

Customers can either use automatic ("touch-free") dispensers or manual dispensers in their facility. Both dispensers can be mounted either with provided screws or with attached tape. Dispensers lock using a key to prevent tampering.



Contact Us

zylastxpinfo@gmail.com
(949) 329-8752



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The information on this website is for educational purposes only. Zylast does not make, and the FDA does not allow from any manufacturer, claims of efficacy against specific bacteria or viruses. For more information, see the [Terms and Conditions](#).

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**EXHIBIT 2 TO
DECLARATION OF
HEATH R. HARLEY**



[Home](#) [Buy Now](#)

Shopping Cart

Details	Name	Unit Price	Quantity	Total	Select
#1A0008-01X	Antiseptic Foaming Soap: 8.25 oz Pump Bottle - 1 Bottle	\$6.81	<input type="text" value="1"/>	\$6.81	
	Family Bundle Pack	\$21.05	<input type="text" value="2"/>	\$42.10	
	Antiseptic Lotion: 0.5 oz Flip Cap Bottle	\$16.40	<input type="text" value="1"/>	\$16.40	
Grand Total:				\$65.31	Delete
Continue Shopping			Update Totals		
Press checkout to enter your customer and shipping information.					
					

ID #: 1394

Contact us info@zylastdirect.com | (213) 545-1848 | Copyright 2013 Zylast Direct | All Rights Reserved. This information is for educational purposes only. Zylast does not make, and the FDA does not approve, claims of effectiveness against specific bacteria or viruses.



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Shopping Cart

Please enter your customer details.

*Full Name:

*Email:

*Address:

*City:

*State:

*Country:

*Zip:

*Phone:

Shipping Details. (If different from above).

Full Name:

Address:

City:

*State:

Country:

*Zip:

Phone:

Miscellaneous

Additional Information:

☐

Remember me.

Use this option to write a cookie to allow us to prepopulate this form the next time you visit.



Allow Promotional Emails

(We will never divulge your email to a 3rd party)

Coupon or Discount Number:

Apply



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BETTER. FASTER. LONGER LASTING PROTECTION !

The Zylast Product Line

Family Bundle Pack

This Family Bundle Pack includes (1) 2 oz Flip Cap Bottle of the Antiseptic Lotion, (1) 8 oz Pump Bottle of the Antiseptic Lotion and (1) 8.25 oz Pump Bottle of the Antiseptic Foaming Soap. You will save 10% by buying all the items together in this Bundle Pack!



Family Pack Bundle

Includes (1) 2oz Flip Cap Bottle of Antiseptic Lotion, (1) 8oz Pump Bottle of Antiseptic Lotion and (1) 8.25oz Pump Bottle of Antiseptic Foaming Soap.

Package: ☒ Single

Price: \$21.05



Antiseptic Lotion



Antiseptic Lotion: 0.5 oz Flip Cap Bottle

This 0.5 oz. 10-pack flip cap bottle is ideal for travel, or to take along in your purse or brief case.

Package: ☒ Case (10)

Price: \$16.40



Antiseptic Lotion: 2 oz Flip Cap Bottle

This 2 oz. flip cap bottle is ideal for travel, or to take along in your purse or brief case.

Package: ☒ Single ☐ Case (24)

Price: \$4.16



Antiseptic Lotion: 8 oz Pump Bottle

Your 8 oz. pump bottle provides the same individual uses as 40 oz of the leading competitor! Perfect for home or work.

Package: ☒ Single ☐ Case (12)

Price: \$12.98



Antiseptic Lotion: 33.8 oz Cartridge

Refill your manual or automatic dispenser with these economical cartridges. See dispensers below.

Package: ☒ Single ☐ Case (6)

Price: \$47.19



Antiseptic



Antiseptic: 2 oz Flip Cap Bottle

This 2 oz. flip cap bottle is ideal for travel, or to take along in your purse or brief case.

Package: ☒ Single ☐ Case (24)

Price: \$4.16



Antiseptic: 8 oz Pump Bottle

Your 8 oz. pump bottle provides the same individual uses as 40 oz of the leading competitor! Perfect for home or work.

Package: ☒ Single ☐ Case (12)

Price: \$12.98



Antiseptic Foaming Soap



Antiseptic Foaming Soap: 8.25 oz Pump

Your 8.25 oz. pump bottle.



Antiseptic Foaming Soap: 33.8 oz Cartridge

Refill your manual or automatic dispenser with these economical cartridges. See dispensers below.

Package: ☒ Single ☐ Case (12)

Price: \$6.81



Package: ☒ Single ☐ Case (6)

Price: \$27.66



Dispensers



Auto Dispenser: White

Your Auto Dispenser senses a users hand movement to provide the perfect shot of Zylast every time. (cartridges sold separately)

Package: ☒ Single ☐ Case (12) (\$990.00)

Price: \$82.50



Manual Dispenser: White

Manual Dispensers require a simple touch to give users just the right amount of Zylast. (cartridges sold separately)

Package: ☒ Single ☐ Case (12) (\$264.00)

Price: \$22.00



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**EXHIBIT 3 TO
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Zylast



Home

Your family's health is your number one priority. Zylast provides the protection you need exactly where you need it most...on you!

[more ▶](#)


School

Germes...a never ending battle for schools. Illness can be costly and disruptive. Keep kids and teachers healthy and in class...

[more ▶](#)


Work

Your business moves fast, but germs move faster. You can't afford to have your key players out just when you need them most...

[more ▶](#)


Travel

Planes, hotels, cruise ships or wherever you go, germs are there. Stay protected while you're on-the-go with Zylast!

[more ▶](#)

on in illness-related absenteeism when students use Zylast.

Unlike alcohol-based sanitizers that lose their

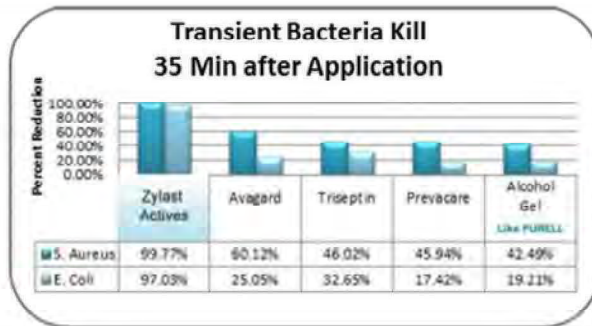
Zylast Outperforms Leading Brands

Get the Science
Behind the Magic ▶



ORDER TODAY
Stay Germ-Free
with Zylast! ▶

Zylast Saves Money!



8 oz of Zylast = 40 oz of Purell



*Based on published usage data from the Purell website and Zylast technical usage data.

Find Us



8

What Fans Are Saying

"There are three primary reasons for the reduction in illness with the Zylast technology. First, the Zylast products are persistent for six hours, so users are protected beyond the 15-second lifespan of an alcohol sanitizer. Second, the Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among children, and germs against which alcohol sanitizers are relatively ineffective. Finally, the product is water-based and moisturizes the hands, so staff actually like using it, which greatly improves compliance."

Beth McNichol, PhD, Emerging Infectious Disease

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A Revolution in Hand Hygiene

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Persistence - A Valuable Attribute

The FDA says: "Persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings, and is important to a safe and effective healthcare personnel handwash."

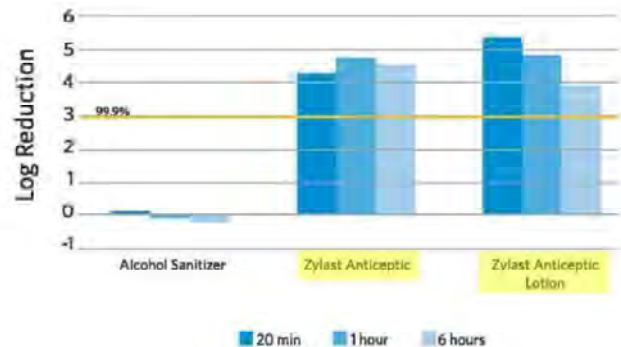
However, standard alcohol sanitizers have no persistent effect - once they evaporate, after about 15 seconds, the hands can immediately become recontaminated.

Zylast has been tested for persistent effect, demonstrating more than a 99.9% kill level 6 hours after application in independent testing.

*Czerwinski et al, 2016

[Read More](#)

Reduction of Transient E. coli on Human Skin



About Zylast

Zylast is a revolution in hand hygiene. Offering rapid, broad-spectrum kill of germs and persistence, Zylast has been tested in hospitals, nursing homes, and schools. With water-based and non-flammable options, Zylast is the perfect choice for any setting!

The patented technology in Zylast was called a 'breakthrough innovation' by experts from the CDC, White House, USAID, and Pentagon in winning a prestigious award.

[More About Zylast](#)

The Zylast Difference

- Rapid, Broad-Spectrum Kill:** Tested and shown to kill more than 99.9% of germs on contact.
- Persistent:** Alcohol sanitizers are useless as soon as they evaporate, after about 15 seconds. All Zylast products are persistent.
- Moisturizing:** Zylast actually adds moisture back into the skin, improving overall hand feel by 46% over alcohol sanitizers.
- Clinically Tested:** Zylast has been tested in clinical trials in hospitals, schools, and nursing homes to see how it performs in real-world settings.
- Cost Savings:** Zylast gets 5 times more uses out of a bottle than a standard alcohol sanitizer, resulting in big savings for our customers!

Testimonials

"Before switching to Zylast, my hands were dry, cracked and bleeding. In less than a week, they've never felt better."

-Jacque H, LPN

[More Testimonials](#)



Contact Us

zylastxpinfo@gmail.com
(949) 329-8752



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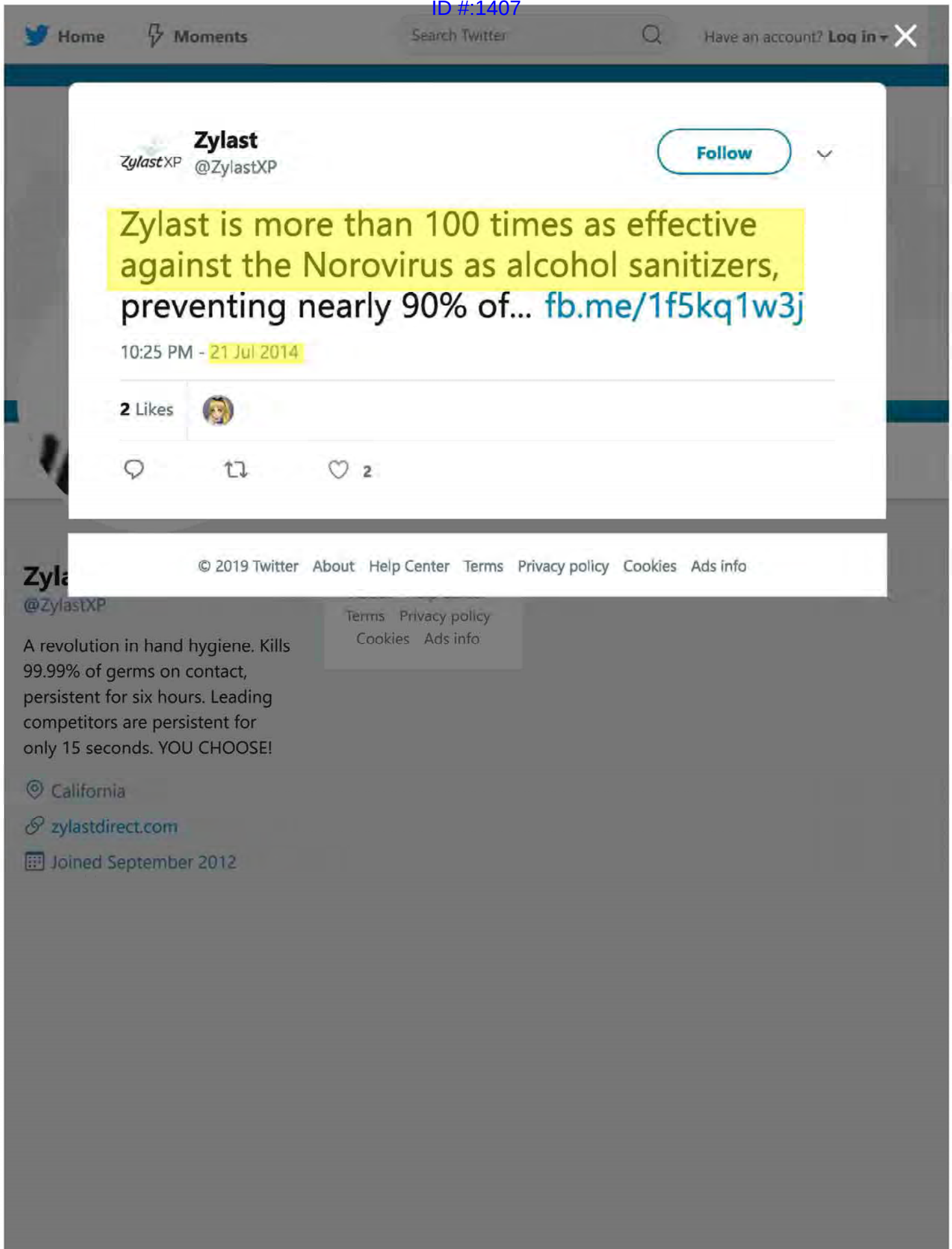
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ZylastXP

December 15, 2014 · 🌐

With Zylast winning the National Fighting Ebola Grand Challenge, we want to offer the same protection to all of our customers over the flu season. Head to ZylastDirect.com and use the coupon code FightingEbola to save 10% on Zylast. Makes a great stocking stuffer!

👍 3

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BUSINESS INFO

Founded in June 2011

Mission

Innovative BioDefense is a company dedicated to relentlessly pursuing advances in hand hygiene and the highest level of customer service.

CONTACT INFO

Call +1 888-306-0316

lbdinfo@zylast.com


http://www.zylast.com

MORE INFO

About

Zylast is a line of hand sanitizers and soaps that is persistent for six hours - alcohol sanitizers only last for 15 seconds!

ZylastXP™ is a product of Innovative BioDefense, Inc. IBD was formed in June of 2011 by a team of experts in the development and sales of medical devices. With a patented, revolutionary matrix that gives long-lasting antimicrobial kill while reducing skin irritation, IBD has developed has developed the first complete line of hand hygiene products: Antiseptic Antiseptic Wipes, Foaming Hand Soap, and



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Awards

Fighting Ebola Grand Challenge Winner! Selected by experts from the CDC, White House Science Office, and the Department of Defense, Zylast was one of only 3 winners out of 1,500 applicants to prevent the spread of Ebola.

Products

Antiseptic Lotion: With the soft, smooth feel of a high-end lotion, the Antiseptic Lotion moisturizes the hands while providing long-term protection from germs. Because it does not have the dangers of an alcohol-based sanitizer – flammability, skin irritation, and accidental ingestion – it is perfect for schools, nursing homes, businesses, and anywhere else a traditional sanitizer is used. Studies have shown that adding a product like our Antiseptic Lotion can reduce the number of children's sick days at school by 40%. And, because so much less is needed to protect the hands, the Antiseptic Lotion offers significant, long-term savings to our customers!

Antiseptic: An alcohol-based sanitizer that kills germs on contact, is persistent for six hours, and more than 100 times as effective as alcohol sanitizers against the Norovirus, all while reducing skin irritation.

Foaming Hand Soap: Built around the patented Zylast technology, the Foaming Hand Soap kills germs that are on the skin and keeps on killing to offer extended protection. With reduced skin irritation, a pleasantly subtle aroma, and a soft feel on the hands, the Foaming Hand Soap is the perfect solution to replace harsh soaps in medical facilities and businesses.

Surgical Scrub: The ZylastXP Surgical Scrub exceeds the minimum FDA requirements for a surgical scrub by more than 10 times! Tested head-to-head against other products like Avagard, the Surgical Scrub has been shown to be the premier surgical scrub in the marketplace today. Offering immediate kill and a persistent effect at six hours, the Surgical Scrub is a powerful and cost-effective way for hospitals and surgery centers to keep their patients safe.

Health/Beauty

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**EXHIBIT 6 TO
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Tested by independent laboratories across the country, Zylast™ is truly a revolution in hand hygiene. After testing the product, researchers at Pace University concluded, "No comparable product is capable of providing the degree of the long term protection exhibited by the Zylast® hand sanitizers."

Zylast technology was shown to kill more than 99.99% of 25 different, FDA-specified germs within 15 seconds, including:

- Staph. aureus
- E. coli
- H. influenzae
- S. marcescens
- Acinetobacter baumannii
- Pseudomonas aeruginosa
- Staph. Epidermis
- E. faecium

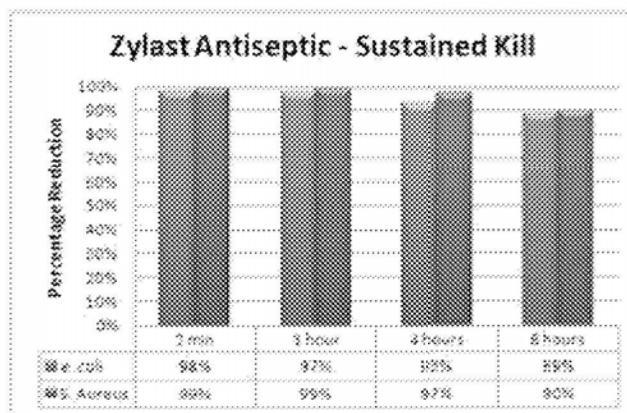
Microorganism	Avagard D Hand Sanitizer*	Zylast Antiseptic**
Staphylococcus aureus	99.1%	99.9997%
Staphylococcus epidermis	99.9%	99.9996%
Klebsella pneumoniae	99.9%	99.9999%
Pseudomonas aeruginosa	99.9%	99.9999%
E. coli	99.9%	99.9999%
Streptococcus pyogenes	98.0%	99.9999%

*Technical Information Bulletin, 3M, Avagard D Hand Sanitizer

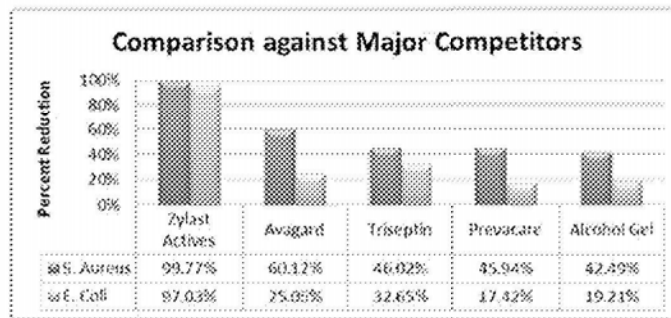
**Time-Kill Testing, BioScience Laboratories, 9/12/2012

"Recent tests show that more than 99.99 percent of disease-causing germs were destroyed within 15 seconds, making Zylast the most effective antimicrobial on the market"
– Senior Living Topics

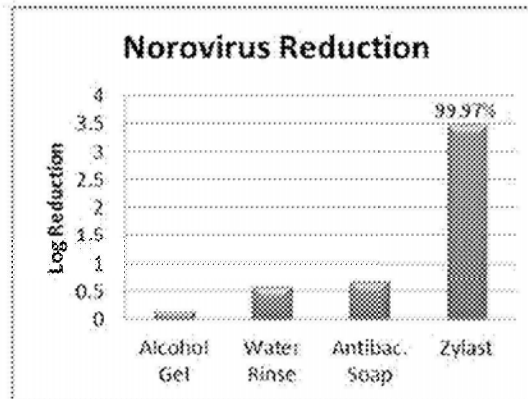
Most soaps and sanitizers only work for 15 seconds – after that, hands can immediately become recontaminated. All Zylast products offer persistence for 6 hours.



Other products claim persistence, or multiple hours of protection. But as the testing shows, the active ingredients in Zylast have been shown to be far superior to any other product on the market!



Norovirus is a dangerous germ that causes the "stomach flu." It is very dangerous, especially when many people are in close quarters, like schools, nursing homes, airplanes, military barracks, or cruise ships. Alcohol is of very little use – in fact, it's even less effective than just rinsing hands with plain water! This is why a recent study showed that nursing homes that use alcohol sanitizers are 6 times more likely to have a Norovirus outbreak than those that rely on handwashing alone. Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!



Adding Zylast Antiseptic Lotion and Foaming Soap to schools was shown to reduce illness outbreaks by 87.5% in a 4-month, crossover study. Overall, illness absenteeism was reduced by nearly 40% for students, giving them another 3-4 healthy school days each year. Teacher illness was reduced by 24.3%.

MRSA is a dangerous, drug-resistant bacteria that is a growing issue in hospitals, nursing homes, prisons, gyms, and in communities. Zylast was tested against MRSA out to six hours after application, with both products destroying more than 90% of MRSA one hour after they had been applied.

**EXHIBIT 7 TO
DECLARATION OF
HEATH R. HARLEY**



PRODUCTS

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- E. coli
- H. influenzae
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- Acinetobacter baumannii
- Pseudomonas aeruginosa
- Staph. Epidermis
- E. faecium

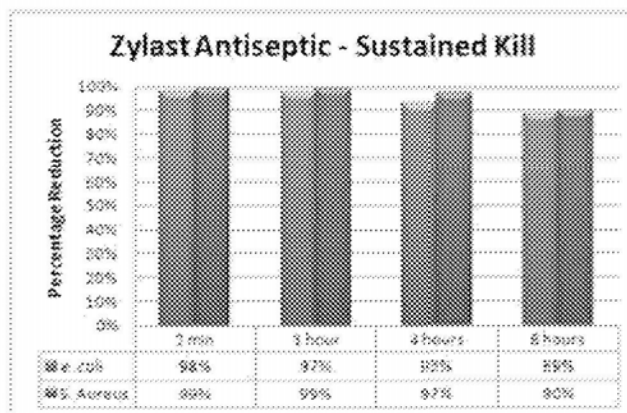
Microorganism	Avagard D Hand Sanitizer*	Zylast Antiseptic**
Staphylococcus aureus	99.1%	99.9997%
Staphylococcus epidermis	99.9%	99.9996%
Kleibisella pneumoniae	99.9%	99.9999%
Pseudomonas aeruginosa	99.9%	99.9999%
E. coli	99.9%	99.9999%
Streptococcus pyogenes	98.0%	99.9999%

*Technical Information Bulletin, 3M, Avagard D Hand Sanitizer

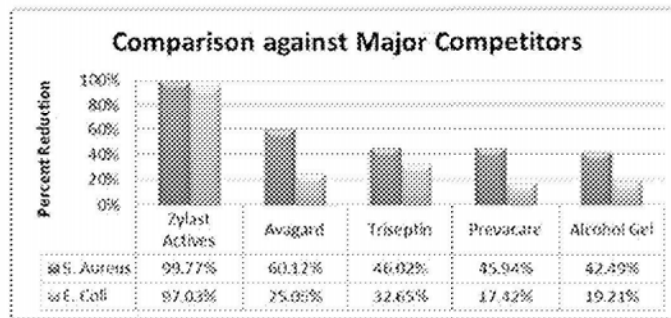
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"Recent tests show that more than 99.99 percent of disease-causing germs were destroyed within 15 seconds, making Zylast the most effective antimicrobial on the market"
– Senior Living Topics

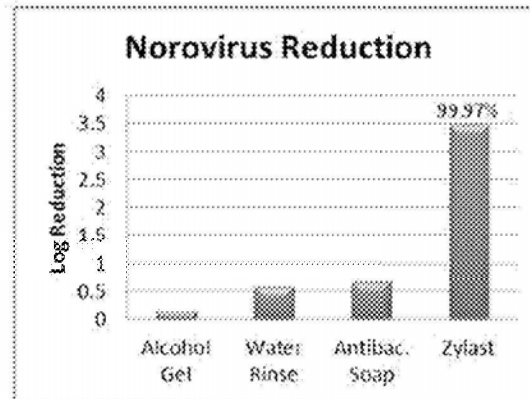
Most soaps and sanitizers only work for 15 seconds – after that, hands can immediately become recontaminated. All Zylast products offer persistence for 6 hours.



Other products claim persistence, or multiple hours of protection. But as the testing shows, the active ingredients in Zylast have been shown to be far superior to any other product on the market!



Norovirus is a dangerous germ that causes the "stomach flu." It is very dangerous, especially when many people are in close quarters, like schools, nursing homes, airplanes, military barracks, or cruise ships. Alcohol is of very little use – in fact, it's even less effective than just rinsing hands with plain water! This is why a recent study showed that nursing homes that use alcohol sanitizers are 6 times more likely to have a Norovirus outbreak than those that rely on handwashing alone. Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!



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**EXHIBIT 8 TO
DECLARATION OF
HEATH R. HARLEY**



The Zylast Advantage

	Alcohol Sanitizer	Zylast
Rapid Germ Kill	✓	✓
Persistent ¹		✓
Shown to Kill > 99% of Norovirus surrogate ²		✓
Improves hand feel by 46% for healthcare workers ³		✓
Winner of the Fighting Ebola Grand Challenge ⁴		✓

Standard alcohol sanitizers only work until they evaporate (about 15 seconds) and then hands can immediately become recontaminated.

Zylast is different, offering both immediate kill but also persistence, and is the most advanced hand sanitizer ever developed. See the Science Page for more details, or contact us to learn more.

[Read More](#)

1. Czerwinski et al, 2016
 2. Czerwinski & Cozean, 2012
 3. Cozean, 2017
 4. Awarded by experts from the CDC, USAID, White House, and Department of Defense

About Zylast

Zylast is a revolution in hand hygiene. Offering rapid, broad-spectrum kill of germs and persistence, Zylast has been shown to reduce illness in hospitals, nursing homes, and schools. With water-based and non-flammable options, Zylast is the perfect choice for any setting!

Winner Fighting Ebola Grand Challenge: Because of persistent efficacy, testing against viruses, and clinical studies showing a reduction in illness outbreaks, Zylast was awarded a winner by experts from the CDC, White House, USAID, and the Pentagon as a "breakthrough innovation" in hand hygiene.

[More About Zylast](#)

The Zylast Difference

- **Rapid, Broad-Spectrum Kill:** Tested and shown to kill more than 99.9% of germs on contact.
- **Persistent:** Alcohol sanitizers are useless as soon as they evaporate, after about 15 seconds. All Zylast products are persistent.
- **Moisturizing:** Zylast actually adds moisture back into the skin, improving overall hand feel by 46% over alcohol sanitizers.
- **Clinical Benefit:** Shown to reduce hospital infections by 23.1%, illness in schools by 39%, and illness outbreaks by almost 90% when used in real-world settings.
- **Cost Savings:** Zylast gets 5 times more uses out of a bottle than a standard alcohol sanitizer, resulting in big savings for our customers!

Testimonials

"Not only has Zylast been able to successfully combat the spread of infection, but our staff has eagerly adopted the product."

-Ryan O., Atlantis Rehabilitation Facility

[More Testimonials](#)



Contact Us

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 (888) 306-0316



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The Zylast Advantage

	Alcohol Sanitizer	Zylast
Rapid Germ Kill	✓	✓
Persistent ¹		✓
Shown to Kill > 99% of Norovirus surrogate ²		✓
Improves hand feel by 46% for healthcare workers ³		✓
Winner of the Fighting Ebola Grand Challenge ⁴		✓

Standard alcohol sanitizers only work until they evaporate (about 15 seconds) and then hands can immediately become recontaminated.

Zylast is different, offering both immediate kill but also persistence, and is the most advanced hand sanitizer ever developed. See the Science Page for more details, or contact us to learn more.

[Read More](#)

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[More About Zylast](#)

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Testimonials

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-Ryan O., Atlantis Rehabilitation Facility

[More Testimonials](#)

**EXHIBIT 10 TO
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Zylast

A Revolution in Hand Hygiene

Buy Now

Visit ZylastDirect.com to order

Testimonials

Hear what others are saying about the Zylast products, the most advanced hand hygiene products ever developed!

Haskins Laboratory, Pace University

"No comparable product is capable of providing the degree of long term protection exhibited by the Zylast hand sanitizers."

"The Zylast Foaming Soap performed significantly better than any other product evaluated in long-term, sustained kill against transient bacteria. Even after it has been washed from the skin, the Zylast product killed all of the challenge organism at 2 minutes and 1 hour after application, which may have significant clinical benefits for users."



Troy Harris, Risk Management, Westmont College

"Our decision to install Zylast reflects Westmont's ongoing commitment to the health, safety and success of our students. Zylast will be a helpful part of our overall strategy to minimize disruption to classes and campus activities."

Jacque H., LPN

"Before switching to Zylast, my hands were dry, cracked and bleeding. In less than a week, they've never felt better."



Leslie Christ, Director, Autism Academy

"Zylast is remarkable; as soon as we installed it we noticed our classrooms were full and our teachers healthier. I love that it's all natural and not flammable, and our kids love using it. It's so important, especially with special needs children, to keep them in the classroom as much as possible. Our parents and teachers even requested that we sell Zylast at our front desk."

Beth McNichol, PhD

"First, the Zylast products are persistent for six hours, so children are protected beyond the 15-second lifespan of an alcohol sanitizer. Second, the Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among children, and germs against which alcohol sanitizers are relatively ineffective. Finally, the product is water-based and moisturizes the hands, so children and staff actually like using it, which greatly improves compliance."



Annie Pryor, PhD, Stop the Stomach Flu

"Zylast Antiseptic is a very exciting new hand sanitizer that kills the norovirus surrogate Feline calicivirus 99.97%! It also possesses some residual activity and has been shown to continue working for about 6 hours against bacteria...I tested the Zylast antiseptic, and it did a great job killing bacteria when you first use it."



Contact Us

IBDInfo@Zylast.com
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Testimonials

Hear what others are saying about the Zylast products, the most advanced hand hygiene products ever developed!

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"The Zylast Foaming Soap performed significantly better than any other product evaluated in long-term, sustained kill against transient bacteria. Even after it has been washed from the skin, the Zylast product killed all of the challenge organism at 2 minutes and 1 hour after application, which may have significant clinical benefits for users."



Troy Harris, Risk Management, Westmont College

"Our decision to install Zylast reflects Westmont's ongoing commitment to the health, safety and success of our students. Zylast will be a helpful part of our overall strategy to minimize disruption to classes and campus activities."

Jacque H., LPN

"Before switching to Zylast, my hands were dry, cracked and bleeding. In less than a week, they've never felt better."



Leslie Ghrist, Director, Autism Academy

"Zylast is remarkable; as soon as we installed it we noticed our classrooms were full and our teachers healthier. I love that it's all natural and not flammable, and our kids love using it. It's so important, especially with special needs children, to keep them in the classroom as much as possible. Our parents and teachers even requested that we sell Zylast at our front desk."

Beth McNichol, PhD

"First, the Zylast products are persistent for six hours, so children are protected beyond the 15-second lifespan of an alcohol sanitizer. Second, the Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among children, and germs against which alcohol sanitizers are relatively ineffective. Finally, the product is water-based and moisturizes the hands, so children and staff actually like using it, which greatly improves compliance."





Annie Pryor, PhD, Stop the Stomach Flu

"Zylast Antiseptic is a very exciting new hand sanitizer that kills the norovirus surrogate Feline calicivirus 99.97%. It also possesses some residual activity and has been shown to continue working for about 6 hours against bacteria...I tested the Zylast antiseptic, and it did a great job killing bacteria when you first use it."

**EXHIBIT 12 TO
DECLARATION OF
HEATH R. HARLEY**



Testimonials

Hear what others are saying about the Zylast products, the most advanced hand hygiene products ever developed!

Haskins Laboratory, Pace University

"No comparable product is capable of providing the degree of long term protection exhibited by the Zylast hand sanitizers."

"The Zylast Foaming Soap performed significantly better than any other product evaluated in long term, sustained kill against transient bacteria. Even after it has been washed from the skin, the Zylast product killed all of the challenge organism at 2 minutes and 1 hour after application, which may have significant clinical benefits for users."



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**EXHIBIT 13 TO
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Zylast

A Revolution in Hand Hygiene

Buy Now

Visit ZylastDirect.com to order

Zylast Products



Antiseptic Lotion 0.2% BZT

Water-based, non-flammable and moisturizing, the Antiseptic Lotion provides rapid, broad-spectrum kill and persistent protection, without irritating the skin.

The Antiseptic Lotion is shown to actually add moisture back into the skin, and improved skin condition by 46% over an alcohol sanitizer when used in a hospital setting. It is the first non-alcohol product to exceed the reference alcohol product in rapid kill testing, and is persistent in the FDA-required testing at six hours.

Available in 1/2 oz tubes, 2 oz bottles, 8 oz bottles, and 1 liter cartridges used inside the proprietary Zylast auto or manual dispensers.



Antiseptic 76% Ethyl Alcohol

The Zylast Antiseptic is an alcohol-based sanitizer, designed for use in hospitals and medical facilities. Unlike traditional alcohol sanitizers, the Zylast Antiseptic offers persistence, demonstrated in testing conducted at six hours after application.

It is also designed with moisturizers and emollients to restore moisture to the skin and reduce irritation with multiple uses. The Zylast Antiseptic is the first hand sanitizer proven to reduce hospital-acquired infection in a controlled, crossover clinical trial.

Available in 2 oz bottles (pictured above), 8 oz bottles, and 1 liter cartridges used inside the proprietary Zylast auto or manual dispensers.



Foaming Soap 0.2% BZT

The Zylast Antiseptic Foaming Soap uses the same proprietary Zylast technology to provide a rapid, broad-spectrum kill of germs with persistence. Filled with moisturizers, it leaves the hands feeling silky and smooth. A light, pleasant citrus scent lingers after use.

When compared against other soaps on the market, the Zylast Foaming Soap showed substantially better persistent effect when tested against both *E. coli* (gram negative) and MRSA (gram positive) bacteria in testing conducted at Pace University.

Available in an 8.25 oz pump bottle (pictured above) and in a 1L cartridge to be used inside the proprietary Zylast auto or manual dispensers.



Surgical Scrub 76% Ethyl Alcohol

The Zylast Surgical Scrub is a waterless, alcohol-based scrub that is designed for use between patients, after the surgeon has scrubbed in with a water-aided rinse.

The Zylast Surgical Scrub kills germs on contact and provides persistence for the surgeon and staff. Alcohol-based surgical scrubs have been demonstrated to be substantially less irritating to the skin than traditional surgical scrubs and just as effective in removing germs. Zylast compares favorably in both performance and price to other surgical scrubs on the market.

Available in a 1L cartridge used inside the proprietary Zylast dispensers.



Automatic and Manual Dispensers

Zylast uses proprietary, ADA-compliant wall-mounted dispensers.

**EXHIBIT 14 TO
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Zylast Products



Antiseptic Lotion 0.2% BZT

Water-based, non-flammable and moisturizing, the Antiseptic Lotion provides rapid, broad-spectrum kill and persistent protection, without irritating the skin.

The Antiseptic Lotion is shown to actually add moisture back into the skin, and improved skin condition by 46% over an alcohol sanitizer when used in a hospital setting. It is the first non-alcohol product to exceed the reference alcohol product in rapid kill testing, and is persistent in the FDA-required testing at six hours.

Available in 1/2 oz tubes, 2 oz bottles, 8 oz bottles, and 1 liter cartridges used inside the proprietary Zylast auto or manual dispensers.



Antiseptic 76% Ethyl Alcohol

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Foaming Soap 0.2% BZT

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Available in an 8.25 oz pump bottle (pictured above) and in a 1L cartridge to be used inside the proprietary Zylast auto or manual dispensers.



Surgical Scrub 76% Ethyl Alcohol

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Available in a 1L cartridge used inside the proprietary Zylast dispensers.



Automatic and Manual Dispensers

Zylast uses proprietary, ADA-compliant wall-mounted dispensers.

Customers can either use automatic ("touch-free") dispensers or manual dispensers in their facility. Both dispensers can be mounted either with provided screws or with attached tape. Dispensers lock using a key to prevent tampering.



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**EXHIBIT 15 TO
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The Science

Zylast is truly a revolution in hand hygiene, and is one of the most extensively tested products on the market. In clinical studies, Zylast has reduced illness in hospitals, nursing homes, and schools.

Proven Clinical Benefit

Zylast has proven to be superior to traditional alcohol sanitizer in several settings. In a study in hospitals, replacing a traditional alcohol sanitizer with Zylast reduced hospital-acquired infections (HAIs) by 20%. In the same study, the staff also noted that using Zylast significantly improved how their hands felt, reducing dryness (24%) while improving skin appearance (41%) and overall hand feel (40%).

This is the first clinical study in which a specific leave-on sanitizer has been demonstrated to reduce nosocomial infections over an alcohol sanitizer.

*Cozean J, Czerwinski S, Cozean C. Reduction of Hospital-Acquired Infections with the Use of a Hand Sanitizer with Both Immediate and Persistent Antimicrobial Effect. *Q. Jour. of Inf. Diseases & Epidemiology*, 1:1; 22-27, 2017



Reducing Illness in Nursing Homes

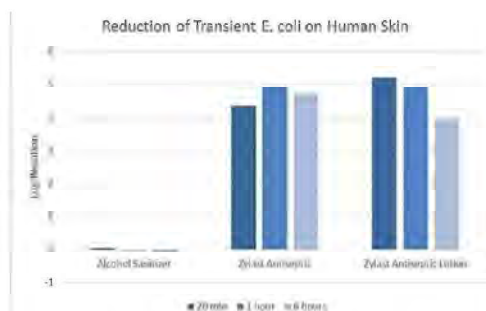
In a clinical study, alcohol-based sanitizers in a long-term care facility were replaced with persistent Zylast Antiseptic. Making this change significantly reduced nosocomial infections. Overall, infections were down by 17%, with significant reductions in upper respiratory tract infections, ears/eyes/nose/throat infections, and other infections.

*Czerwinski S & Cozean J. Use of a Persistent, Water-Based Hand Sanitizer with Anti-Viral Properties Reduces Nosocomial Infection in Long Term Care Facility. *J. Immunol Tech Infect Dis*, 6:3, 2017

Persistence

The FDA says: "Persistence, defined as prolonged activity, is a **valuable attribute that assures antimicrobial activity** during the interval between washings, and is important to a safe and effective healthcare personnel handwash." However, standard alcohol sanitizers have no persistence. Zylast has been tested for persistent effect, demonstrating more than a 99.9% kill level 6 hours after application in independent testing.

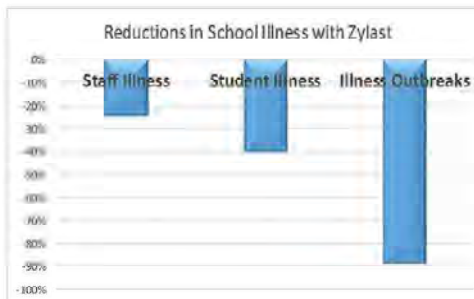
*Czerwinski S, Cozean J, Taylor J, McGovern K, Cozean C. Novel Persistent Products Significantly Reduce In-Vitro Transmission of Transient Pathogens. *BIT Annual Global Health Conference*, 2016.



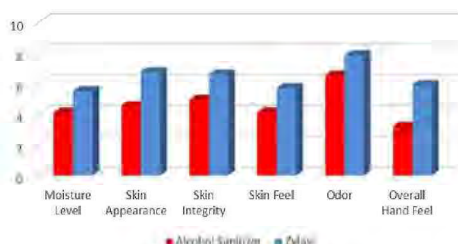
Reducing Illness Outbreaks by 87.5%

Zylast was tested in schools for its ability to prevent illness absenteeism and outbreaks. In the two schools tested, adding Zylast reduced illness absenteeism among students by 39% and among staff by 24%. Even more incredibly, illness outbreaks - when more than 10% of the class was sick - were reduced by nearly 90%.

*Keeney J, Conroy J et al, Reducing Illness Absenteeism and Outbreaks Among Students with Persistent, Water-based Antiseptic Products in a Controlled, Crossover Clinical Study. *Int. J. Microbiol Infect Dis*, 1(2) 2017



Questionnaire Results



Improving the Hands of Healthcare

Healthcare workers use hand sanitizers every few minutes, often more than 100 times each day. Their hands become irritated, cracked, and dry, leading to increased chances for infection among patients and the staff. When a standard alcohol sanitizer was replaced with the Zylast Antiseptic Lotion, the Overall Hand Feel[®] of workers went up by 46%. In fact, there was an improvement with Zylast in every category studied. Zylast adds moisture back into the skin and was shown to reduce irritation over alcohol sanitizers in medical settings.

*Conroy J, Czerwinski J, Conroy J. Reduction of Hospital-Acquired Infections with the Use of a Hand Sanitizer with Both Immediate and Persistent Antimicrobial Effect. *Q. Jour. of Inf. Diseases & Epidemiology*, 1:1, 22-27, 2017

Reducing Hospital-Acquired Infections

Alcohol sanitizers have been shown to make hand hygiene faster and improve compliance, but have never been demonstrated in a controlled, crossover clinical trial to reduce HAIs (Doebeling et al, 1992; Larsen et al, 2005; Rupp et al, 2008). Zylast is the first hand sanitizer to reduce hospital infections in the same trial, showing a reduction of 23.1% in nosocomial infections in a hospital trial of more than 6,000 patients.

*Conroy J & Kampitab A controlled, crossover study of a persistent antiseptic to reduce hospital-acquired infection, *AJID*, 9(1): 6-9, 2014



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